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Gas permeable vs gas impermeable contact lenses and their compared effects on the cornea

Robert Rothbard
Pacific University

Ron Schaeffer
Pacific University

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Abstract

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LYNN J. COON., O.D.

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ROBERT ROTHBARD

RON SCHAEFFER

Accepted by the faculty of the College of Optometry, Pacific University, in partial fulfillment for the Doctor of Optometry Degree.

A
Midterm Grade

A
Final Grade

LYNN J. COON, O.D.

THESIS ADVISOR

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a-Term is defined in report.

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ABSTRACT

A study was completed comparing the differences in effect of gas permeable contact lenses (Polycon) vs gas impermeable contact lenses (PMMA). Eleven subjects were chosen, each of whom were to wear a Polycon lens on one eye and a PMMA lens on the other eye. Keratometric findings, refraction, visual acuity, edema and the endothelial mosaic were measured at varying stages of wear. It was shown that there was significantly less edema with the Polycon lens. Also it was found that the slides taken of endothelial cells could not be read as well when the eye photographed was wearing a PMMA lens (as opposed to the Polycon lens). It therefore appears that more corneal change is taking place when a PMMA lens is worn than when a Polycon lens is worn.

For approximately the last thirty years the material used in hard contact lenses has been almost exclusively polymethylmethacrylate (PMMA). With the exception over the last few years of cellulose acetate butyrate (CAB), silicone lenses, and soft lens materials, the gas impermeable PMMA lens has been the lens material of choice to fit most patients with. Although CAB, silicone lenses and soft lenses are gas permeable, therefore seemingly advantageous, drawbacks keep them from becoming the contact lens material of choice. One fault concerning the CAB lens is that its base curve has a tendency to warp upon hydration.[1] With the silicone lens there is an incompatability of the lens with the eye due to the hydrophobic nature of silicone.[2] A disadvantage with soft lenses include decreased acuity as a function of astigmatism.

Two years ago the Food and Drug Administration (FDA) approved a new gas permeable material, Polycon (silafocon A), which is composed of 30% silicone and 70% PMMA. A study run by Finnemore and Korb showed that the PMMA lens caused edema in 96% of the eyes tested while the Polycon lens caused edema in only 16% of the eyes observed, even though the lenses were of exactly the same physical parameters.[3] Too, Williams showed that the Polycon lens possessed more base curve stability than PMMA lenses. One disadvantage of the Polycon lens is its difficulty in wetting because of the 30% silicone.[4]

Edema in part is caused by a hypoxic state of the cornea existing due to contact lens coverage. This hypoxic situation may be revealed as changes in the corneal endothelial mosaic. Holden and Zantos cite how immediate insertion of contact lenses in unadapted patients cause "small, black, blister like eruptions (blebs) displacing or obscuring the endothelial cells." Holden and Zantos point out these changes are only transient as when the person adapts to the contact lens, the mosaic is restored more toward its original pattern.[5] These changes were both viewed and photographed over periods of time.

There are currently two methods used for viewing the corneal endothelium. One utilizes the specular microscope[6] and the other employs a biomicroscope with specular reflex.[7] Comparing the two systems, the specular microscope is applanated on the cornea, while in the other system there is no corneal contact. Photographic information concerning these two systems may be employed to record the corneal mosaic and changes that occur.[8]

Changes occur in the mosaic throughout life. As one gets older the density of endothelial cells decreases with a concomitant increase in cell size.[9] Also there may be a change in the mosaic as a result of trauma. As stated by Rao, et al, where an area of cornea is traumatized as a result of intraocular lens implant, the affected endothelial area will at first have no cells present, after which a migration of cells from adjacent areas will take place.[10] These cells will be larger in structure. It should be noted that in humans there appears to be no mitosis of endothelial cells occurring in the cornea. However, there exists a mitosis of endothelial cells in rabbit corneas.[11]

If the corneal endothelium is compromised so that it could no longer extrude excess fluid through its pumping system, edema would result. The endothelium by an active process, keeps the stroma from imbibing fluid. The mechanism of a pumping system is cited in <u>Investigative Ophthalmology and Visual Science</u>.[12] The edema occurring as a result of first time contact lens insertion could be due in part to the transient endothelial changes.

The following study will quantitatively measure endothlial cell density as a function of oxygen permeability properties of the contact lens material used. The property of a lens to transmit oxygen to the cornea is a function of both the permeability of the lens' material to oxygen and its thickness. Rofojo showed the oxygen transmitted through a lens to the cornea doubles as its thickness is reduced by 50%. This was true of both hard and soft lenses.[13] Due to its stability, Polycon lenses are able to achieve a thin central thickness, facilitating oxygen flow to the cornea.

A previous study monitoring endothelial mosaic change as a function of contact lens wear (PMMA) was done by Stonecypher and Lo. In general their study did not show any significant change in the corneal mosaic.[14]

This study will explore the effect a gas permeable contact lens (Polycon) material has on endothelial structure as opposed to a non-gas permeable material (PMMA). Polycon and PMMA lenses of exactly the same dimensions (base curve, overall diameter, optic zone diameter, peripheral curves, thickness and power) were fit to twenty-two eyes. Quantitative differences in the endothelial mosaic as a function of lens material will be determined.

Also, changes in corneal toricity, corneal edema and subjective refraction as well as the endothelial mosaic and visual acuity were investigated as a function of the lens material.

Eleven myopic subjects were chosen for this study. The range of spheroequivalent refractive errors for the twenty-two eyes studied was -0.75D to -7.25D with an average spheroequivalent of -2.82D. The subjects either never wore contact lenses or would have been out of their old contact lenses for a period of at least two months. This helped to insure good baseline data for observing endothelial change. The subjects were screened for corneal as well as overall ocular health.

For each subject, one eye was fit with a Polycon lens and the fellow eye was fit with a PMMA lens. Six of the subjects were chosen to wear the PMMA lens on their left eye with the Polycon lens worn on the right eye while five of the subjects were chosen to wear the Polycon lens on their left eye with the right eye wearing the PMMA lens. This wearing requirement lasted until all photographic measurements were completed, which was within two weeks of the initial dispensing. After this time, the PMMA lens was exchanged for another Polycon lens of similar design. To avoid patient confusion of which lens was PMMA and which lens was Polycon, the PMMA lens was marked (dotted).

To monitor the endothelial changes, a 35mm Nikon single reflex camera was mounted on a Nikon biomicroscope. Photographs were taken at 35X magnification, using Kodachrome 64 film. When aligning the camera, a 5X Galilean telescope was utilized in an effort to consistently measure the same area of endothelium over the course of the study. Vertical and horizontal controls were established with the telescopic system so that its position remained constant for each patient. By aligning Purkinje Image #1 (corneal catoptric image from the fixation light, which is mounted in the same horizontal plane as the telescope) in the center of the telescope reticule, a fairly accurate replication of the central endothelium can be monitored for each photograph.[15] Figure 1 shows the relationship between the telescope and the biomicroscope.

Figure 1 (top view)

1) Microscope

2) Light source for biomicroscope

3) Telescope (20^{o} rotation inward from straightahead position)

4) Fixation light (attached to telescope)

A scale was attached to the fixed unit upon which the biomicroscope rests. Since the telescope position may have to be altered for different patients, the location of the telescope for the initial baseline photographs was noted for each eye. Therefore, when the future photographs were taken, reliable and consistent positioning occurred.[16]

Corneal endothelial photographs of both eyes were taken at the following times:

1) before the lenses were inserted (baseline information)
2) after 6 hours of continuous wear
3) after 12 hours of continuous wear
4) after 14 hours of continuous wear
5) after 1 hour of sleep (or eyes closed for 1 hour) following 13 hours of continuous wear (13*1).

Following each of the above periods, corneal and ocular integrity was monitored and evaluated.

In analyzing the data, a comparison of baseline photographs to all subsequent photographs was made. To insure against any biased results, an "experimenter blind" approach was used; when analyzing the pictures, the researchers did not know whether the picture was taken of an eye wearing a Polycon lens or a PMMA lens. In measuring the pictures, a determination of endothelial cell density, as described by Sperling and Gundersen was used.[17]

The analysis of counting the endothelial cells was accomplished by projecting an endothelial mosaic slide onto a constructed counting grid. The grid was constructed by photographing a hemacytometer slide at the same plane where the subjects' corneas were photographed. Both the cornea and the hemacytometer slide were photographed at the same magnification (35X) Each square unit of the hemacytometer slide measured $4x10^{-2}mm^2$. Therefore when the endothelial mosaic was projected onto the grid, the number of cells/mm^2 would be multiplied by 25. However, the distance from the projector to the grid was later doubled, while the same constructed grid was used, therefore a multiplication factor of 100 ($25x2^2$) was used.

Although four pictures were taken of each eye, we were not able to read all of them in some cases. This was due to the indistinctness of the endothelial mosaic. Also when the slide was projected onto the counting grid (Figure 2), either 1, 2, or 3 of the individual square sections were counted. When "#" is cited, this is the total number of square sections counted combining all the pictures read (as appears in Table 5).

In analyzing the photographs counted, all the square sections (which were converted to cells/mm^2) for a particular eye for that particular wearing session were averaged ($\bar{x}$) and a standard deviation (σ) generated. From this a comparison factor for that particular eye, $(100)\sigma/\bar{x}$ was derived.

In the study, all contact lenses utilized had an 8.5mm overall diameter and a 7.0mm optic zone diameter. The power range of all contacts fitted was from -1.00D to -6.00D. The secondary curves had a width of 0.65 mm with a radius of 0.5mm flatter than the base curve. The peripheral zone was 0.1mm wide with a 17.0mm curvature. The central thickness of all lenses was 0.08mm.

Lenses were designed for minimal central clearance fit, the base curve usually 0.25 to 0.50 diopters steeper than the flattest corneal meridian as measured by the keratometer. The design was verified by biomicroscopic interpretation of the fluorescein pattern.

Other areas of change monitored throughout the study were keratometric findings, corneal edema, visual acuity (measured with the best refraction in place without contact lenses worn), and changes in refraction as measured by the subjective to best visual acuity (labeled as 7A). All of these changes will be compared across the lens type at each stage of lens wear. Measurements for keratometric findings, edema, and refraction were not made during the final period of wear.

Edema was evaluated as follows[A]:

Grade	Description
0	No observable edema
1	Very light density; no defined borders; no stain.
2	Light density; some definition of borders; no stain

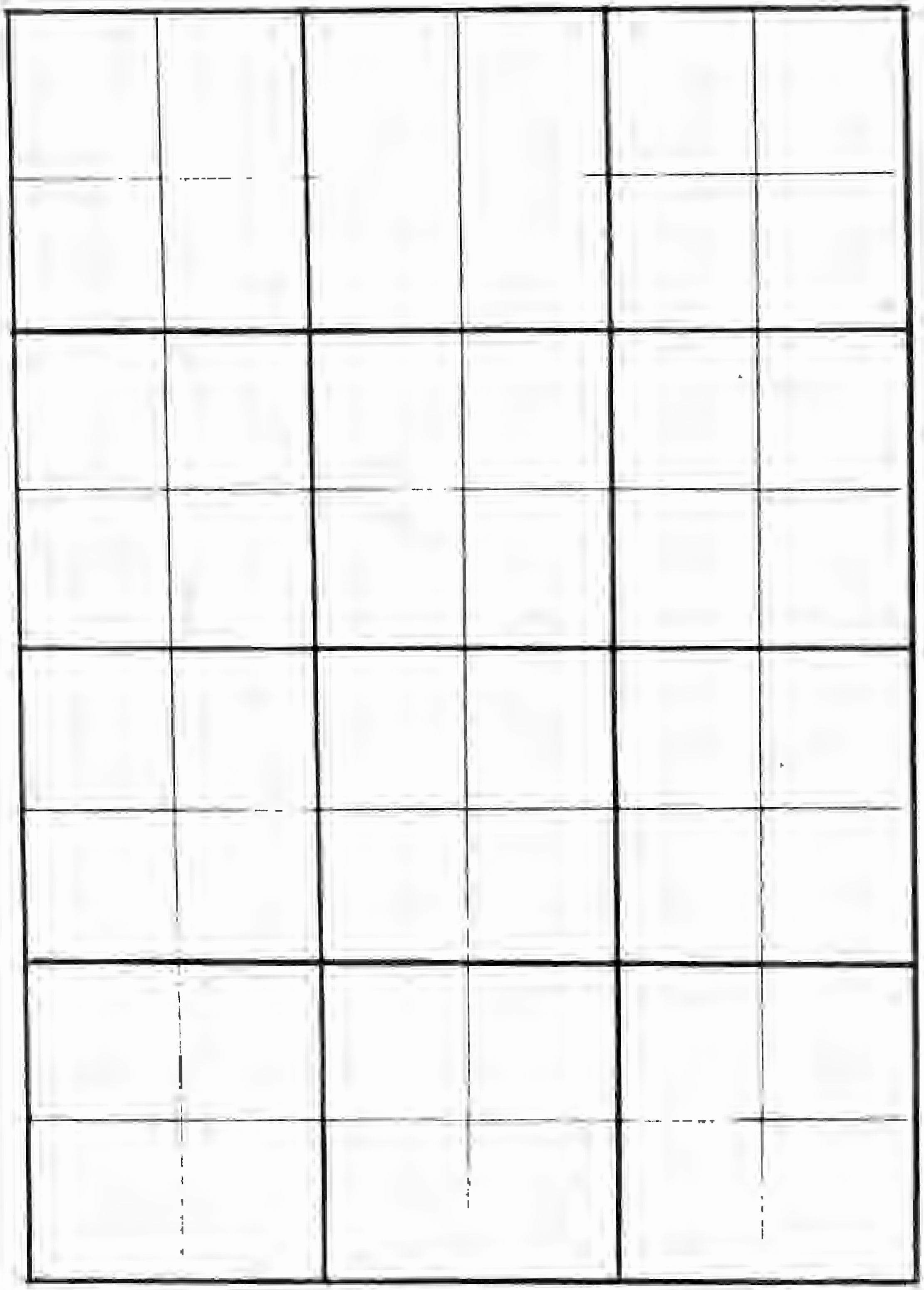
Grade	Description
3	Medium density; borders well defined; beginning epithelial breakdown but no staining.
4	Dense; localized or generalized; edematous corneal lines; epithelial breakdown and staining; dimple veiling.

A-This grading system is that of Ronald L. Kerns, O.D., as given to us in Contact Lens I class notes.

Figure 2: Grid on which endothelial cells were counted

Code:

Cells/mm²:



Data concerning subjective refraction to best visual acuity (7A), keratometric findings, edema, endothelial cell density and visual acuity (measured with the refraction in place without contact lenses worn) were recorded.

Baseline data concerning keratometric findings, refraction findings and edema findings were recorded in Table 1. Table 8 shows baseline visual acuity as well as the visual acuities for the subsequent wearing sessions. In analyzing the data, all findings for the 6 hour, 12 hour and 14 hour wearing sessions were compared to the baseline figures. (13*1 data only included findings for endothelial cell change. Keratometric findings, refraction findings, edema findings and visual acuity findings, are not described.)

Table 2 portrays changes in keratometric findings, refraction and edema grade during the 6 hour wearing session. It was found that the eyes wearing PMMA lenses had keratometric findings that increased by an average of 0.70D and 0.75D in the horizontal and vertical meridians, respectively, while the horizontal and vertical meridians for the corneas wearing Polycon lenses steepened by 0.64D and 0.44D, respectively. For the same wearing period, the 7A refraction increased in the myopic direction by 0.70D in the horizontal meridian while the change in the vertical meridian was 0.45D in the myopic direction when the PMMA lens was worn as compared to the Polycon lens where there was an increase in the myopic direction of the horizontal meridian by 0.35D and no change in average refraction in the vertical meridian. With respect to edema for the 6 hour wearing session, there was an average increase of 1 full grade of edema from baseline when the PMMA lens was worn as opposed to a grade increase of 0.15 grade for eyes wearing Polycon lenses.

The same type of comparison of data was made for the 12 hour wearing period and is portrayed in Table 3. When the PMMA lens was worn, the average keratometric change in the horizontal meridian was 0.62D while the vertical meridian steepened by 0.60D while the average change in corneal curvature for Polycon lenses was 0.53D and 0.24D of steepening in the horizontal and vertical meridians, respectively. The 7A refraction showed an average increase in the myopic direction of 0.22D and 0.08D in the horizontal and vertical meridians when the PMMA lens was worn as opposed to an increase in the hyperopic direction of 0.06D and 0.42D in the horizontal and vertical meridians when the Polycon lens was worn. When edema findings were compared, there was an average increase from baseline data of 1 full grade of edema for the eyes wearing the PMMA lens compared to an increase of 0.19 of a full grade of edema in the eyes wearing the Polycon lens.

Data for the 14 hour wearing session is portrayed in Table 4.

It shows the average keratometric change in corneal curvature for eyes wearing PMMA lenses is a steepening of 0.89D and 0.51D in the horizontal and vertical meridians, respectively. The corneas also showed steepening in both horizontal and vertical meridians when Polycon lenses were worn, 0.50D and 0.40D, respectively. With respect to the refraction, the horizontal and vertical meridians showed an increase in the myopic direction of 0.34D and 0.31D, respectively, when the PMMA lens was worn as opposed to an increase in the myopic direction of 0.25D in the horizontal meridian and an increase in the hyperopic direction of 0.19D in the vertical meridian when the Polycon lens was worn. The average increase in edema grade from baseline during the 14 hour wearing session was 1.69 for corneas wearing PMMA lenses while the average increase in edema grade of corneas wearing Polycon lenses was 0.28D.

The ability to read endothelial slides of a particular eye was measured by the factor $100\sigma/\bar{x}$. It was found the average $100\sigma/\bar{x}$ for PMMA lenses was 18.47 while the average $100\sigma/\bar{x}$ for Polycon lenses was 11.04. These two findings were derived from the values in Table 7. Table 7 values were derived from Tables 5 and 6.

Table 8 contains the visual acuities recorded throughout the study. They were recorded in decimal form (20/20 equals 1.00, 20/40 equals 0.50, etc.) with the best refraction in place without any contact lenses worn.

Table 1. Tabulation of Baseline Findings for Eleven Subjects

Patient	Eye	Lens worn	K*findings	7A[a]	Edema grade
H.S.	OD	PMMA	44.12/44.75@90	-6.75-1.00x80	0
	OS	Polycon	44.50/44.37@90	-6.00-0.75x105	0
M.S.	OD	Polycon	43.25/44.75@90	-3.50-1.50x005	0
	OS	PMMA	43.62/45.00@90	-4.00-0.50x170	0
S.K.	OD	Polycon	44.75/45.25@90	-0.50-0.75x116	0
	OS	PMMA	45.00/45.12@90	-1.00-0.75x62	0
E.H.	OD	PMMA	43.75/46.00@90	-1.00-2.00x175	0
	OS	Polycon	44.00/46.50@85	-3.75-2.75x175	0
J.D.	OD	PMMA	40.50/41.87@105	-0.50-2.00x20	0
	OS	Polycon	40.00/42.25@90	-0.50-2.25x170	0
C.G.	OD	PMMA	44.37/44.50@102	-2.25 sphere	0
	OS	Polycon	44.37/44.37@90	-2.50-0.50x75	0
L.A.	OD	Polycon	44.00/43.50@90	-0.75-1.50x92	0
	OS	PMMA	45.12/43.75@90	-0.25-2.25x85	0
J.K.	OD	Polycon	44.00/44.12@80	-3.25-0.75x170	0
	OS	PMMA	44.12/44.50@90	-2.25-0.50x78	0
C.S.	OD	PMMA	44.50/43.75@102	-0.50-1.25x75	0
	OS	Polycon	44.50/44.50@90	-0.75 sphere	0
E.E.	OD	Polycon	43.50/43.75@72	-4.00-0.75x167	0
	OS	PMMA	43.62/44.25@86	-4.00-1.25x170	0
F.C.	OD	Polycon	42.37/42.25@90	-0.50-1.00x72	0
	OS	PMMA	42.75/43.75@90	-0.75-0.75x145	0

*-Keratometric readings of corneal curvature.
a-The term 7A was defined earlier in the paper.
b-Subjective edema grading is discussed in Table 8.

Table 2. Tabulation of Change of Findings After 6 Hours of Wear

Patient	Eye	Lens worn	Change in K findings a H	b V	Change in 7A H	V	Edema grade
			c	d	e	f	
H.S.	OD	PMMA	0.37	0.50	0.75	-0.25	1
	OS	Polycon	0.00	0.00	1.25	1.25	0
M.S.	OD	Polycon	-0.75	-0.75	-0.25	0.50	0
	OS	PMMA	-0.62	-0.37	-0.25	0.00	1
S.K.	OD	Polycon	0.25	-0.25	-0.25	-0.25	0.5
	OS	PMMA	0.00	0.00	0.50	0.50	0.5
E.H.	OD	PMMA	1.25	2.00	-3.75	-3.75	2.5
	OS	Polycon	0.25	0.00	-0.75	0.75	0
J.D.	OD	PMMA	1.87	0.62	-2.00	-1.50	1.5
	OS	Polycon	1.00	0.25	-2.00	-1.75	0.5
C.G.	OD	PMMA	1.37	1.75	0.75	0.75	0
	OS	Polycon	2.12	1.12	1.00	0.25	0
L.A.	OD	Polycon	0.50	1.75	-1.75	0.25	0
	OS	PMMA	1.87	2.00	-1.75	-0.50	2.5
J.K.			Data was not taken				
C.S.	OD	PMMA	1.00	0.50	-0.75	-0.50	0
	OS	Polycon	0.25	0.25	-0.75	-1.00	0
E.E.	OD	Polycon	1.37	0.12	0.25	0.25	0
	OS	PMMA	0.12	0.75	-0.50	0.75	1
F.C.	OD	Polycon	1.37	1.87	-0.25	-0.25	0.5
	OS	PMMA	-0.25	-0.25	0.00	0.00	0

a-Horizontal meridian (extending from 136-45 inclusive).
b-Vertical meridian (extending from 46-135 inclusive).
c-Keratometric change without a sign in front indicates a steepening of corneal curvature.
(Symbol explanation completed on next page.)

d-Keratometric change with a "-" indicates a flattening in corneal curvature.
e-7A change without a sign in front indicates a less myopic finding or increase in hyperopia.
f-7A change with a "-" in front indicates an increase in myopia or decrease in hyperopia.

Table 3. Tabulation of Change of Findings After 12 Hours of Wear

Patient	Eye	Lens worn	Change in K findings		Change in 7A		Edema grade
			H	V	H	V	
H.S.	OD	PMMA	0.37	-0.62	0.50	-0.50	2
	OS	Polycon	0.12	-0.37	1.00	1.00	0
M.S.	OD	Polycon	1.00	1.25	0.00	0.50	1
	OS	PMMA	1.37	1.25	-0.25	-0.25	1
S.K.	OD	Polycon	0.25	-0.25	-0.25	0.50	0
	OS	PMMA	0.00	0.00	-0.25	0.50	0
E.H.	OD	PMMA	1.50	2.25	-2.25	-2.00	2
	OS	Polycon	0.25	-0.50	-0.25	0.75	0
J.D.			Data was not taken.				
C.G.	OD	PMMA	1.87	1.25	0.25	-0.25	0.5
	OS	Polycon	1.62	1.62	1.50	1.50	0
L.A.	OD	Polycon	no reading		-1.75	0.25	no reading
	OS	PMMA	no reading		-1.75	-0.50	no reading
J.K.	OD	Polycon	0.50	-0.62	-1.50	-1.50	0.5
	OS	PMMA	0.00	-0.37	0.50	0.25	0.5
C.S.	OD	PMMA	0.00	0.50	-0.50	0.00	1.5
	OS	Polycon	0.25	0.25	0.75	-0.25	0
E.E.	OD	Polycon	0.25	0.50	1.00	1.00	0
	OS	PMMA	-0.12	0.50	1.75	2.00	0.5
F.C.			Data was not taken.				

Table 4. Tabulation of Change of Findings After 14 Hours of Wear

Patient	Eye	Lens worn	Change in K findings H	Change in K findings V	Change in 7A H	Change in 7A V	Edema grade
H.S.	OD	PMMA	2.87	1.00	0.25	-0.50	0.5
	OS	Polycon	1.50	1.37	1.50	1.00	0.5
M.S.	OD	Polycon	-0.25	-0.75	no reading		0
	OS	PMMA	-0.37	-0.50	no reading		1
S.K.	OD	Polycon	no reading		no reading		0
	OS	PMMA	no reading		no reading		1
E.H.	OD	PMMA	1.50	2.00	-1.25	-1.00	3
	OS	Polycon	0.25	0.00	0.00	1.25	0
J.D.	OD	PMMA	2.00	0.12	-2.75	-1.75	4
	OS	Polycon	1.00	0.25	-4.25	-3.00	0.5
C.G.	OD	PMMA	0.12	0.75	0.75	0.00	0.5
	OS	Polycon	0.12	-0.12	0.25	-0.25	1
L.A.			Data was not taken.				
J.K.	OD	Polycon	0.00	0.12	2.25	2.25	0
	OS	PMMA	0.37	0.00	0.75	0.50	2
C.S.	OD	PMMA	1.87	0.75	-0.25	-0.25	no reading
	OS	Polycon	1.50	2.00	0.25	-0.75	no reading
E.E.	OD	Polycon	0.00	0.75	1.00	1.00	0
	OS	PMMA	0.12	0.75	0.75	1.25	0.5
F.C.	OD	Polycon	0.37	0.00	-1.00	-1.00	0.5
	OS	PMMA	-0.50	-0.25	-1.00	-0.75	2

Table 5. Tabulation of Endothelial Cells-Average and Variance

Patient	Eye	Baseline			6 Hours			12 Hours			14 Hours			13*1 Hours		
		$\bar{x}$ a	σ b	# c	$\bar{x}$	σ	#	$\bar{x}$	σ	#	$\bar{x}$	σ	#	$\bar{x}$	σ	#
H.S.	OD	2733	58	3	3267	321	3	3180	192	4	3250	129	4	3243	190	7
	OS	2900	0	2	3000	0	2	3300	141	3	3300	141	3	3250	212	3
M.S.	OD	3100	100	3	2933	58	3	3125	222	12	3075	50	4	3317	160	6
	OS	3200	173	3	3100	141	2	3100	82	4	not readable			3167	158	3
S.K.	OD	2968	58	3	3100	100	3	3075	171	4	not present			2925	158	6
	OS	2700	100	3	2980	205	5	3250	71	2				3214	168	7
E.H.	OD	2800	141	2	2667	153	4	2800	187	5	2629	170	7	2480	286	5
	OS	2600	100	2	2667	58	3	2860	152	5	2767	151	6	2875	171	4
J.D.	OD	3375	150	4	3233	58	3	not present			3280	295	5	not present		
	OS	3400	0	2	3300	100	3				3300	141	5			
C.G.	OD	3325	150	4	3250	71	2	3383	471	2	3300	100	3	3240	89	5
	OS	3150	173	4	3367	58	3	3150	71	6	3300	141	2	3550	129	4
L.A.	OD	2350	129	5	2600	82	4	2525	150	4	not present			2800	100	3
	OS	2500	0	2	2500	264	3	2700	264	3				3100	208	7
J.K.	OD	3100	0	2	2900	141	2	3233	153	3	3133	58	3	3050	71	2
	OS	3100	141	2	3200	141	2	3225	96	4	3100	255	5	3300	82	3
C.S.	OD	3400	141	2	2980	130	5	3140	195	5	2725	237	4	2888	275	8
	OS	3025	96	4	3167	58	3	3171	180	7	3325	139	8	3180	175	9
E.E.	OD	2871	198	7	3143	140	7	2950	71	4	3114	212	3	3033	208	5
	OS	2900	141	2	2800	0	1	3100	82	2	not readable			2950	58	4
F.C.	OD	3050	129	4	3160	89	5	not present			3267	153	2	3400	141	2
	OS	3250	71	2	3167	115	3				3420	110	8	3214	308	[illegible]

a-Symbol is described on page 9. b,c-Symbols described on page 9.

Table 6. 100(Standard Deviation/Average Density of Cells/mm^2)

Patient	Eye	Lens worn	Baseline	6 Hours	12 Hours	14 Hours	13*1 Hours
H.S.	OD	PMMA	2.12	9.82	6.04	3.97	5.86
	OS	Polycon	0.00	0.00	4.27	4.27	6.52
M.S.	OD	Polycon	3.23	1.98	7.10	2.25	4.82
	OS	PMMA	5.41	4.55	2.64	x	5.22
S.K.	OD	Polycon	1.95	3.22	5.56	x	5.40
	OS	PMMA	3.70	6.88	5.26	x	5.22
E.H.	OD	PMMA	5.04	5.74	6.68	6.46	11.50
	OS	Polycon	3.85	2.17	5.31	5.53	5.95
J.D.	OD	PMMA	4.44	1.79	x	8.99	x
	OS	Polycon	0.00	3.03	x	4.27	x
C.G.	OD	PMMA	4.51	2.18	13.90	3.03	2.75
	OS	Polycon	4.49	1.72	2.25	4.27	3.63
L.A.	OD	Polycon	5.48	3.15	5.94	x	3.57
	OS	PMMA	0.00	4.00	9.77	x	6.71
J.K.	OD	Polycon	0.00	4.86	4.73	1.85	2.23
	OS	PMMA	4.55	4.40	2.98	8.22	2.48
C.S.	OD	PMMA	4.14	4.36	6.21	8.70	9.52
	OS	Polycon	3.17	1.83	5.68	4.18	5.50
E.E.	OD	Polycon	6.90	4.45	2.41	6.81	6.86
	OS	PMMA	0.00	4.00	9.77	x	6.71
F.C.	OD	Polycon	4.23	2.82	x	4.68	4.14
	OS	PMMA	2.18	3.63	x	3.12	9.58

Table 7. Combined 100(Standard Deviation/Average Density of Cells/mm^2) for 13*1 Hours, 14 Hours, 12 Hours, and 6 Hours Minus the Baseline Readings

Patient	Eye	Lens worn	Total
H.S.	OD	PMMA	23.57
	OS	Polycon	15.06
M.S.	OD	Polycon	10.67[a]
	OS	PMMA	7.00
S.K.	OD	Polycon	12.23
	OS	PMMA	13.66
E.H.	OD	PMMA	25.34
	OS	Polycon	15.11
J.D.	OD	PMMA	6.34
	OS	Polycon	7.30
C.G.	OD	PMMA	17.35
	OS	Polycon	7.38
L.A.	OD	Polycon	7.18
	OS	PMMA	20.48
J.K.	OD	Polycon	13.67
	OS	PMMA	13.53
C.S.	OD	PMMA	24.65
	OS	Polycon	14.02
E.E.	OD	Polycon	6.82 b
	OS	PMMA	20.48
F.C.	OD	Polycon	7.41
	OS	PMMA	14.15

a,b-Total did not include any readings from the 14 Hour wearing period.

Figure 3. Histograms depicting data from Table 7 for both PMMA and Polycon lenses (1 inch equals a value of 20)

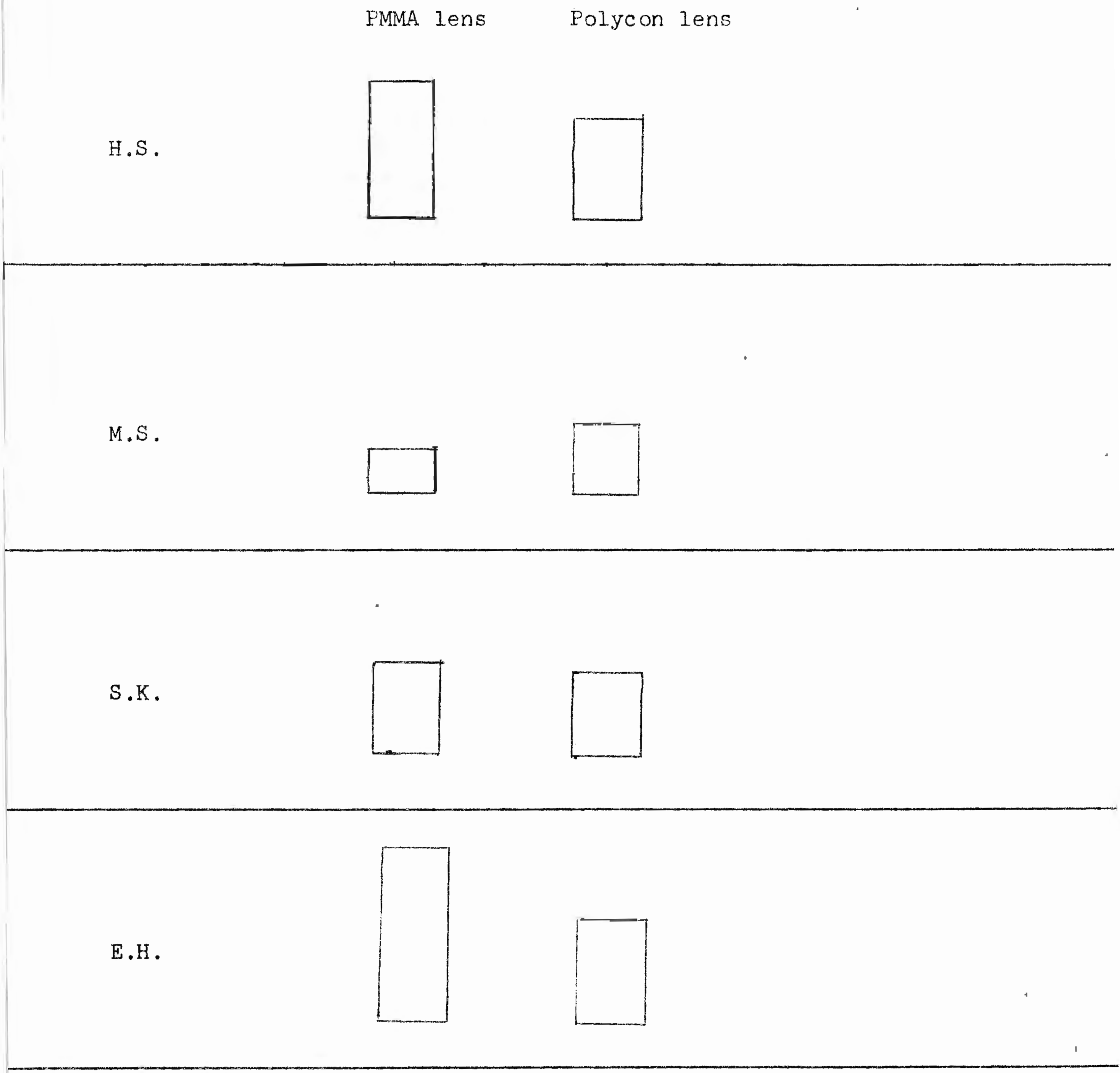


Figure 3 continued.

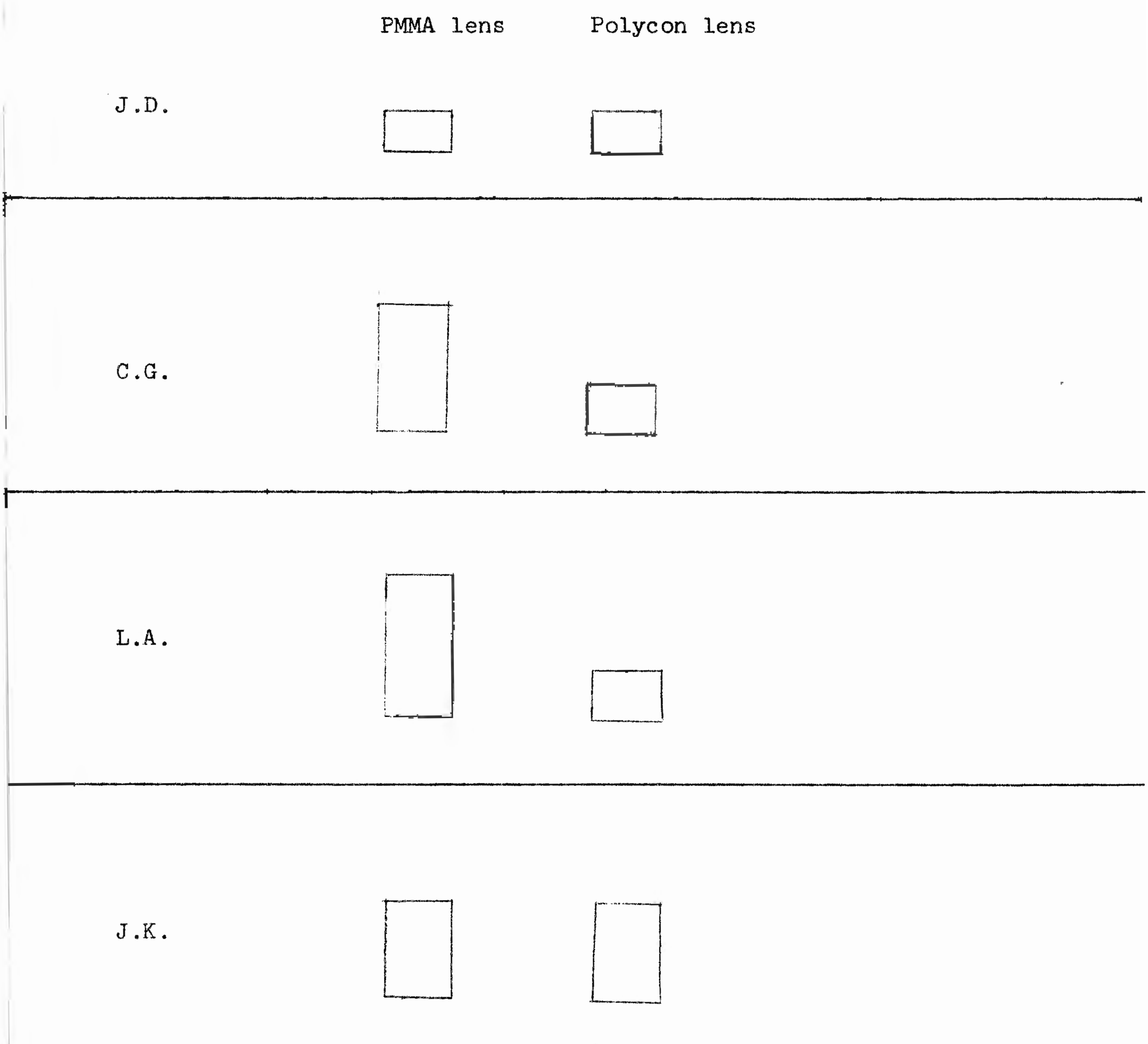


Figure 3 continued.

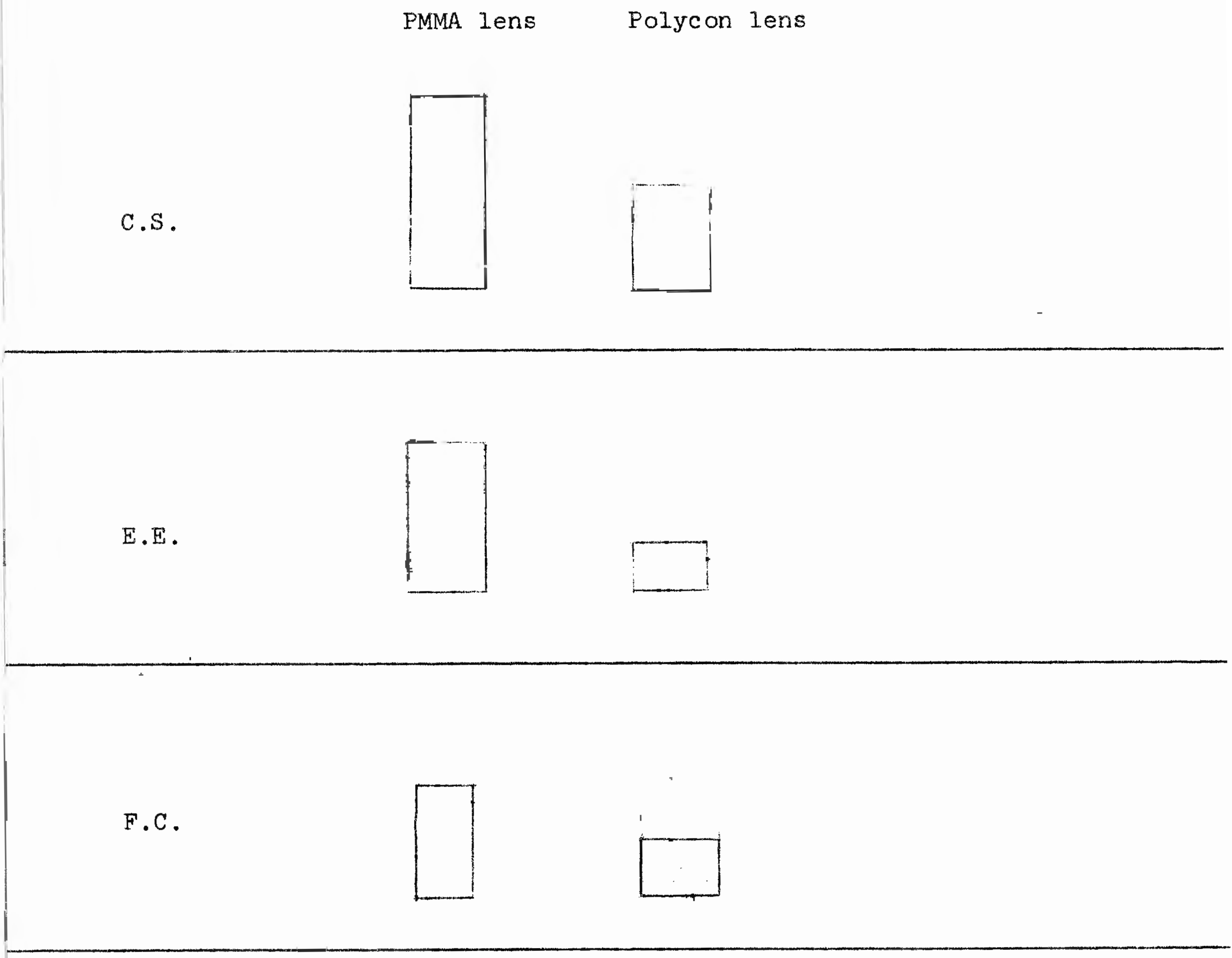


Table 8. Visual Acuities, As Taken Through 7A Refraction, Without Any Contact Lenses Worn

Patient	Eye	Lens worn	Baseline	6 Hours	12 Hours	14 Hours
H.S.	OD	PMMA	0.80	1.00	1.00	1.00
	OS	Polycon	0.80	1.33	1.00	1.00
M.S.	OD	Polycon	1.33	1.00	x	1.33
	OS	PMMA	1.33	1.00	x	1.33
S.K.	OD	Polycon	1.33	1.33	1.00	x
	OS	PMMA	1.33	1.33	1.00	x
E.H.	OD	PMMA	0.80	1.00	0.67	1.00
	OS	Polycon	1.00	1.00	1.00	1.00
J.D.	OD	PMMA	1.00	0.80	x	0.80
	OS	Polycon	0.40	0.67	x	0.67
C.G.	OD	PMMA	1.00	1.00	1.00	1.33
	OS	Polycon	1.33	1.33	1.00	1.33
L.A.	OD	Polycon	1.33	x	x	x
	OS	PMMA	1.33	x	x	x
J.K.	OD	Polycon	1.00	x	x	1.00
	OS	PMMA	1.33	x	x	1.33
C.S.	OD	PMMA	1.33	1.00	1.33	1.33
	OS	Polycon	1.33	1.00	1.33	1.33
E.E.	OD	Polycon	1.33	x	1.00	1.33
	OS	PMMA	1.33	x	1.00	1.33
F.C.	OD	Polycon	1.33	1.33	x	1.33
	OS	PMMA	1.33	x	1.00	x

DISCUSSION AND CONCLUSIONS

Differences in change (from baseline) pertaining to keratometric findings, refraction, edema, visual acuities, and endothelial mosaic were analyzed as a function of contact lens material worn. The T test for signifigance was used for comparing all data except edema. In this case, the non-parametric Wilcoxson Rank Sum Test was used.

Data in all the above categories was analyzed with respect to the period of wear (6 hours, 12 hours, etc.). In other words changes in baseline findings with Polycon lenses during the 6 hour period of wear were compared with changes occurring at the same period of time with PMMA lenses. This pairing of data for all measurement periods showed no significant differences in change occurring in keratometric findings or refraction in either horizontal or vertical meridians when changes induced by the two materials were compared. This also held true for measuring visual acuity change. Although there appears to be a significant change in edema, change comparing the PMMA lens and the Polycon lens, during the 6 and 12 hour wearing sessions, statistically, there is no significant difference. This in part was due to the lack of data generated. Regarding visual acuities measured, Table 8 shows there were 3 different eyes in which baseline visual acuities were less than 1.00 where subsequent acuities (6 hour period, 12 hour period, etc.) were equal to or greater than 1.00. Also in only 1 eye measured did the acuities drop off to a level less than 1.00 when the baseline visual acuity started out as 1.00.

Two significant changes did occur using the above method of matched pairing. During the 14 hour wearing period there was significantly less edema occurring ($p < .05$) with Polycon lenses as compared to PMMA lenses. Herein lies a discrepency in the data. One would expect changes in either refraction and/or keratometric findings along with edema change. This did not occur. The second significant change showed that when a T test was run using the values from Table 7, significantly less variability existed ($p < .05$) in reading endothelial slides from eyes wearing Polycon lenses as opposed to reading endothelial slides from eyes wearing PMMA lenses. Since all pictures were assumed to be taken of the same area, this difference in variability was interpreted as meaning one could not read slides of the PMMA mosaics as well as slides from the Polycon mosaics. The fact that the slides could not be read equally could have been due either to an actual change in the endothelial mosaic taking place or edema in the cornea that actually created the reading problem. Since there was more variability in the endothelium of the eyes wearing the PMMA lenses, then there was a temporary change in the apparent mosaic probably due to edema. It could not be determined if the change was artifactual (photographing through edema) or an actual cell change took place. The apparent corneal mosaic change could be a sensitive edema indicator. Long term studies are needed to rule out endothelial cellular change as a function of contact lens wear.

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